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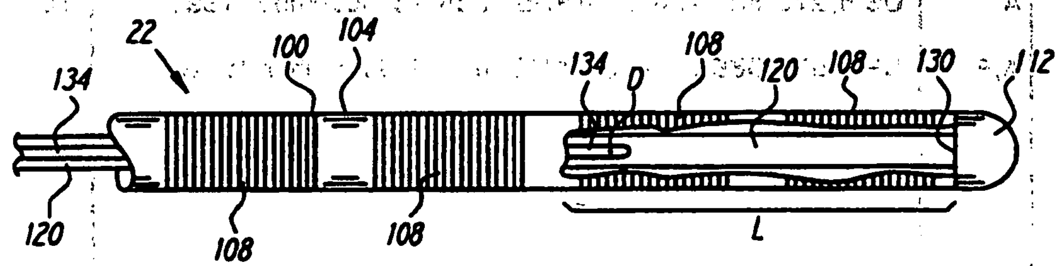


(57) Abstract

The present invention includes improved assemblies for transferring torque from a catheter main body tube (104) to the steering center support member (120) through the buff bond joint assembly. Such improvements include the utilization of a crimp sleeve (290) that is disposed within the butt bond sleeve (274), such that an enhanced mechanical interference is created within the adhesive that is utilized to fill the but bond sleeve. Various crimp sleeve shapes are disclosed. Alternatively, a stiffener member may be fixedly engaged to the steering mechanism, where the stiffener member includes an arm portion that projects into the butt bond sleeve area. The projecting arm portion is bonded into the adhesive that fills the butt bond sleeve. Additional torque enhancing features include radially inwardly project ribs that are formed in the butt bond sleeve, and laterally extending portions of the steering center support member which create enhanced mechanical interference with the adhesive disposed within the butt bond sleeve. The improved steering and control features of the present invention are obtained by locating the attachment point of the steering wires with the center support member a suitable distance proximate to the distal end of the center support member. Additionally, improvements to the shape of the center support member provide enhanced control characteristics. In a preferred embodiment, the steering wire attachment point is located approximately one inch proximal to the distal tip of the device.

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# DESCRIPTION

## Improved Catheter Distal End Assemblies

### Background Of The Invention

### Field of the Invention

The present invention relates generally to catheter devices, and more particularly to mechanisms for enhancing the diagnostic and therapeutic capabilities of such catheter devices by improvements to the steering and control mechanisms of the devices.

### Description of the Prior Art

An important feature in catheter design is the accurate placement of the catheter distal end assembly in relation to the subject's bodily tissue. With specific application to multiple electrode ablation distal end assemblies, it is important that the steering mechanism achieve intimate tissue contact with the plurality of ablation electrodes. Current curvilinear catheters have difficulty in obtaining such tissue contact because they include steering mechanisms which provide steering control at the distal tip of the electrode assembly. The present invention is an improvement over such distal tip steering mechanisms by locating the steering wire engagement to a point proximal of the distal tip, and improving the flexibility of the catheter control support member, thus providing better steering control over the electrode assemblies that are disposed proximal to the distal tip of the end assembly.

To obtain accurate placement of the distal end assembly, the handle is often rotated about its longitudinal axis to twist the main body tube in order to rotate the distal end assembly. In this regard, the torque applied to

the main body tube must be transferred to the distal end assembly through the joinder of the distal end assembly with the main body tube. In current catheters the torque is transferred from the main body tube to the distal assembly primarily through the adhesive bond between the main body tube and the steering mechanism, and secondarily through the butt bond between the main body tube and the distal assembly tube. Both of these torque transfer devices have limitations.

The torque transfer from the main body tubing to the distal tubing is limited by the flexible material characteristics of the distal tubing. If the entire catheter were made of a strong braided main body tubing then the torque to the distal tip would increase, however the flexibility to steer the catheter would decrease. The current distal tubing is soft and flexible for steering, so it is of limited use in transferring torque.

The torque transfer from the main body tubing to the steering mechanism is through an adhesive bond. However, a limitation in this assembly is that the adhesive bond is formed between a round component, the butt bond sleeve, and the outer surface of the steering sleeve. If the bond is incomplete or if the torque is too strong, the adhesive breaks or the steering sleeve tears, freeing the steering mechanism to rotate. Also the steering mechanism may at times freely rotate inside the steering sleeve. This can cause loss of distal torque and possibly barber poling. Mechanisms to improve the bonds at these assemblies are therefore necessary to assure efficient torque transfer from the main body tube to the distal end assemblies.

## Summary Of The Invention

The present invention includes improved assemblies for transferring torque from a catheter main body tube to the steering center support member through the butt bond joint

assembly. Such improvements include the utilization of a crimp sleeve that is disposed within the butt bond sleeve, such that an enhanced mechanical interference is created within the adhesive that is utilized to fill the butt bond sleeve. Various crimp sleeve shapes are disclosed. Alternatively, a stiffener member may be fixedly engaged to the steering mechanism, where the stiffener member includes an arm portion that projects into the butt bond sleeve area. The projecting arm portion is bonded into the adhesive that fills the butt bond sleeve. Additional torque enhancing features include radially inwardly projecting ribs that are formed in the butt bond sleeve, and laterally extending portions of the steering center support member which create enhanced mechanical interference with the adhesive disposed within the butt bond sleeve.

The improved steering and control features of the present invention are obtained by locating the attachment point of the steering wires with the center support member a suitable distance proximate to the distal end of the center support member. Additionally, improvements to the shape of the center support member provide enhanced control characteristics. In a preferred embodiment, the steering wire attachment point is located approximately one inch proximal to the distal tip of the device.

It is an advantage of the present invention that it provides enhanced steering and control characteristics.

It is another advantage of the present invention that enhanced torque transfer is achieved between the main body tube and the distal end assembly.

It is a further advantage of the present invention that an improved center support member is provided which produces enhanced distal end control characteristics.

It is yet another advantage of the present invention that the catheter distal end assembly can be steered into

intimate contact with bodily tissue disposed within a tissue crevasse.

It is yet a further advantage of the present invention that the distal end assembly can be steered into a curved shape wherein the distal end portion is relatively straight.

These and other features and advantages of the present invention will become understood by those skilled in the art upon reading the following detailed description and claims. The applicants intend that the claims cover all such features and advantages as are disclosed herein.

In The Drawings

Fig. 1 depicts a catheter of the present invention including the improved distal end assembly;

Fig. 2 is a side elevational view, with cut away portions, of a prior art distal end assembly;

Fig. 3 is a side elevational view depicting the steering distortion characteristics of the prior art device depicted in Fig. 2;

Fig. 4 is a side elevational view depicting the prior art catheter end assembly disposed in a curved configuration within a section of bodily tissue;

Fig. 5 is a side elevational view depicting the prior art catheter end assembly being reverse steered into a section of bodily tissue;

Fig. 6 is a side elevational view having cut away portions of the improved distal end steering assembly of the present invention;

Fig. 7 is a side elevational view of the device depicted in Fig. 6, showing the steering distortion characteristics thereof;

Fig. 8 is a side elevational view depicting the catheter end assembly of the present invention disposed in a curved configuration with a section of bodily tissue;

Fig. 9 is a side elevational view depicting the catheter end assembly of the present invention being reverse steered into contact with a section of bodily tissue;

Fig. 10 is a side elevational view depicting the utilization of the distal end assembly depicted in Fig. 6 in contact with bodily tissue having a crevasse; and

Fig. 11 is a side elevational view of the tapered center support member of the present invention having a steering wire attached thereto;

Fig. 12 is a side elevational view depicting an alternative center support member of the present invention having a steering wire attached thereto;

Fig. 13 is an enlarged side elevational view having cut away sections, of the prior art catheter distal end butt bond assembly;

Fig. 14 is an end elevational view of the prior art butt bond assembly depicted in Fig. 13, taken along lines 14-14 of Fig. 13;

Fig. 15 is an enlarged side elevational view, having cut away portions depicting an improved torque transfer device of the present invention;

Fig. 16 is an end elevational view of the device depicted in Fig. 15;

Fig. 17 is a perspective view of a U or C-shaped crimp sleeve that is utilizable in the present invention;

Fig. 17A is a perspective view of a G-shaped crimp sleeve that is utilizable in the invention;

Fig. 18 is an end elevational view that is similar to Fig. 16, utilizing the crimp sleeve depicted in Fig. 17;

Fig. 19 is a perspective view of a ribbed butt bond sleeve of the present invention;

Fig. 20 is an end elevational view, similar to Fig. 16, depicting the utilization of the ribbed butt bond sleeve depicted in Fig. 17;

Fig. 21 is a perspective view of the improved steering center support member of the present invention;

Fig. 22 is a perspective view of a proximal portion of an alternative steering center support member of the present invention;

Fig. 23 is an end elevational view similar to Fig. 13 that depicts the utilization of the steering center support member depicted in Fig. 22;

Fig. 24 is an end elevational view, similar to Fig. 23 that depicts the utilization of a ribbed butt bond sleeve of Fig. 19 with the device depicted in Fig. 13;

Fig. 25 is a perspective view of the stiffener member of the present invention;

Fig. 26 is a top plan view of the stiffener member depicted in Fig. 25;

Fig. 27 is a side elevational view of the stiffener member depicted in Fig. 25;

Fig. 28 is an end elevational view of the stiffener member depicted in Fig. 25;

Fig. 29 is an enlarged side elevational view, having cut away portions, similar to Fig. 15, depicting the stiffener member of the present invention in association with the butt bond joint assembly of the present invention;

Fig. 30 is an end elevational view of the device depicted in Fig. 29;

Fig. 31 is an end elevational view, similar to Fig. 30, depicting the utilization of a three ribbed butt bond sleeve in association with the device depicted in Fig. 30;

Fig. 32 is a perspective view of an alternative butt bond sleeve configuration of the present invention;

Fig. 33 is an end elevational view depicting the utilization of the butt bond sleeve depicted in Fig. 32 together with the stiffener member of the present invention as depicted in Fig. 30;

Fig. 34 is a perspective view of a gapped butt bond sleeve that is utilizable with the stiffener member of the present invention.

Detailed Description Of The Preferred Embodiments

The present invention is adapted for use inside body lumens, chambers or cavities for either diagnostic or therapeutic purposes, where access to the interior body region is obtained, for example, through the vascular system or alimentary canal, without complex, invasive surgical procedures. It may be used in diverse body regions for diagnosing or treating diseases. For example, various aspects of the invention have application for the diagnosis and treatment of arrhythmia conditions within the heart. It also has application in the diagnosis or treatment of intravascular ailments, in association, for example, with angioplasty or atherectomy techniques. Various aspects of the invention also have application for diagnosis or treatment of ailments in the gastrointestinal tract, the prostrate, brain, gall bladder, uterus, and other regions of the body. The diverse applicability of the invention in these and other fields of use will become apparent.

With regard to the treatment of conditions within the heart, the present invention 10 is designed to produce intimate tissue contact with target substrates associated with various arrhythmias, namely atrial fibrillation, atrial flutter, and ventricular tachycardia. A physician is able to position the distal section containing the diagnostic and/or ablation electrodes (rings or coils) into contact with tissue and enable reverse steering (as described hereinbelow) to improve tissue contact. It is particularly designed to enable the distal section to conform to nonuniform anatomic regions such as the Eustachian ridge between the inferior vena cava and the tricuspid annulus, especially when the catheter is steered to obtain intimate

tissue contact. In addition, it possesses improved mapping capabilities of the catheter by decreasing the electrode size yet maintaining the ability to produce a variety of lesion sizes including large surface area, deep lesions through simultaneous power delivery to a plurality of electrodes with temperature feedback and control. These improvements enhance the applicability of the catheter to target atrial flutter, atrial fibrillation, other supraventricular tachycardias, and ventricular tachycardia substrates.

The efficient utilization of catheters involves in the first instance the ability to steer and place the catheter distal end assembly in a chosen location relative to the target bodily tissue. Improvements in catheter control and steering capabilities, such as are disclosed herebelow, result in more efficient and effective catheters, which provide improved performance and results. Two specific catheter improvement areas that are described herebelow are improved steering control at the catheter distal end, which improves the diagnostic and therapeutic performance of multiple electrode distal end assemblies, and the improvement of torque transfer between the catheter main body tube and the distal end assembly.

A catheter system 10 of the present invention is depicted in Fig. 1. It includes a handle 14, a system controller 12 that is connected by an electrical cable 16 to the handle 14, a main body tube 18 that is engaged at its proximal end 20 to the handle 14, and a distal end assembly 22, including a section of distal end tubing 24 that is engaged at its proximal end 26 to the distal end 28 of the main body tube 18 at a bond 32, and a tip member 36. A steering mechanism is disposed within the distal end assembly 22 and is interconnected with the handle 14 through steering wires that pass through the main body tube 18. The improvements of the present invention are generally located

within the distal end assembly 22. Applicant's improved electrode and steering mechanisms are next discussed with the aid of Figs. 2 through 12.

Improved steering and control characteristics for a catheter distal end assembly can be advantageously achieved by properly locating the bonding points of the steering wires to the center support. Portions of this concept are described in U.S. Patent 5,273,535, entitled: "Catheter with Electrode Tip Having Asymmetric Left and Right Curve Configurations", the disclosure of which is incorporated herein by reference as though set forth in full. To provide an understanding of the technology relevant to this disclosure, a prior art catheter distal end assembly 60 is generally depicted in Fig. 2. The distal end assembly 60 includes a hollow tubular body portion 64 having a plurality of ablation electrodes 68 disposed along its length. A tip member 72 is disposed at the distal end 76 of the tubular member 64. A thin flat steering center support member 80 is disposed within the central lumen 84 of the tubular member 64, and the tip member 72 is fixedly engaged to the distal end 88 of the center support member 80. Two steering wires 90 and 92 are bonded on opposite sides of the center support member 80 at location P that is located at the distal end 88 of the center support 80, immediately behind the tip member 72 (only wire 90 is shown in this view).

Various positioning control and performance difficulties may be experienced when the prior art device 60 is utilized. As depicted in Fig. 3, certain steering maneuvers, particularly reverse steering, where the tip 72 is deflected a distance A in one direction to make contact with tissue 94, can cause proximal portions 96 of the assembly 60 to extend a distance B in the direction opposite to the movement direction of the tip 72, thus causing a snake-like effect. This effect is undesirable for catheters carrying multiple ablation electrodes because it causes

electrodes in the region 96 to extend away from tissue that is to be treated. This undesirable effect is due to the flexibility of the distal end 60 and apparently results because the point of maximal steering force is proximal to the steering wire attachment point P.

Fig. 4 depicts the prior art device 60 in a curved configuration disposed within a cavity 97 of bodily tissue 94. Such a cavity is representative of a heart ventricle. When the device 60 is steered to an appropriate location within the cavity 97 it is first steered into a curve or loop that is tighter than the inner wall 98 of the cavity 97. Thereafter, as depicted in Fig. 5, it is reverse steered (see arrow 99) to open the loop in order to press the sides of the device 60 against the surface 98. As is depicted in Fig. 5, when the device 60 is reverse steered, such that the tip 72 makes contact with the surface 98 of the tissue 94, the undesirable gap B in region 96 can be created. This results in a less than satisfactory contact of the device 60 with the tissue surface 98 for diagnostic and therapeutic purposes.

Features of the present invention 10 solve this prior art steering problem and produce an improved device. A primary improvement feature is the relocation of the steering wire attachment point away from the distal end 88 of the steering center support member 80. As depicted in Fig. 6, the improved catheter distal end assembly 100 of the present invention includes a tubular body portion 104 having a plurality of electrodes 108 disposed throughout its length. A flat steering center support member 120 is centrally disposed within the tubular member 104 and a tip member 112 is engaged to the distal end 130 of the center support member 120. Two steering wires 134 and 138 are disposed on opposite sides of the center support member 120 (wire 138 is not shown in this view). The steering wires 134 and 138 are affixed (such as by soldering, welding or

bonding) to opposite sides of the center support member 120 at a point D which is located a distance L proximal to the distal end 130 of the center support member 120. In a preferred catheter embodiment having several ablation coil electrodes 108, the distance L is approximately one inch, such that ablation electrodes are located distally to the steering wire attachment point D.

Fig. 7 depicts the deflection profile of the improved catheter end assembly 100. In Fig. 7, the actuation of the steering wires 134 and 138 has caused the tip 112 to deflect a distance E. The location of the steering wire attachment point D produces an advantageous steering profile which increases the force exerted against tissue with the ablation electrodes located proximate to the steering wire attachment point D. In addition, the location of the steering wire attachment point D proximal to the distal tip produces a relatively straight region distal to point D when steering is actuated. For various applications, the portion of the end assembly 100 that is distally located relative to the steering wire attachment point D can be made more or less flexible than other portions of the end assembly 100. The degree of flexibility or stiffness of this distally located portion is a matter of design choice, depending upon the specific application in which the particular catheter end assembly may be utilized.

Fig. 8 depicts the catheter end assembly 100 disposed within a cavity 97 of a body tissue member 94, such as a heart ventricle, and Fig. 9 depicts the device 100 being reverse steered (arrow 99) within the cavity 97. Comparing the movement of the device 100 in Figs. 8 and 9 with the movement of the prior art device 60 depicted in Figs. 4 and 5, it is seen that when the device 100 is reverse steered to achieve intimate tissue contact with the surface 98 that steering the device 100 at point D creates a uniformly intimate tissue contact, which results in improved

diagnostic and therapeutic performance of the present invention 100 over the prior art device 60. The catheter does not lift off the tissue proximal to D because of the spring force of the catheter when it is in its prolapsed position as illustrated in Fig. 9.

Further improvements to the present invention 10 are achieved through the utilization of shorter electrode members 108 that are spaced close together. Additional improvements are achieved through the utilization of a system controller 12 that has the capability to independently provide power to any one or more of the plurality of electrodes 108. The device 10 has the capability to provide enhanced diagnostic and therapeutic results. The shorter electrodes, when used for diagnostic purposes, provide enhanced and more detailed mapping capabilities, and when the shorter more closely spaced electrodes are used for therapeutic purposes, deeper and more continuous lesions can be created.

The improved steering and performance characteristics of the assembly 100 are particularly evident when the device is utilized to map or ablate tissue regions having nonuniform anatomical features, including crevasses such as in the Eustachian ridge region of the heart. In addition, this system enables controllable creation of long, deep lesions which may be located between infarct zones or from an infarct zone to an anatomic barrier. Such a situation is depicted in Fig. 10 wherein a cross-section of tissue 150 is depicted having a crevasse 160 which represents the Eustachian ridge region. The distal end assembly 100 is placed across the crevasse 160, such that the steering wire attachment point D is located approximately in the center of the crevasse 160. When the steering wires are actuated to draw the assembly 100 down into the crevasse 160, the portion 164 of the assembly 100 that is located distal to the attachment point D is forced upwards against one side

168 of the crevasse whereas the portions 172 of the assembly 100 located proximal to the attachment point D are pressed against the other side 176 of the crevasse 160. It is therefore seen that the distal end assembly embodiment 100 advantageously fills and makes intimate contact with tissue on both sides of the crevasse 160.

To better enable the device 100 to fill a crevasse, as depicted in Fig. 10, it can be advantageous that the portions of the assembly 100 proximate the attachment point D be particularly flexible. A preferred steering center support member for this purpose is depicted in Fig. 11, wherein a tapered center support member 180 is shown with a steering wire 138 engaged thereto. As depicted therein, the tapered center support member 180 is formed with a relatively wide proximal section 182, a tapered middle section 184 and a relatively narrow distal end portion 186. A tip member 112 is fixedly engaged to the distal end 130 of the center support 180. The steering wire 138 is attached to the center support 180 in the thin distal portion 186, a distance L from the distal end 130. The attachment point D is therefore located in the most flexible region 186 of the center support member 180. The enhanced flexibility of this steering attachment point enables a distal end assembly utilizing a center support such as support 180 to conform to tissue having ridges and crevasses, such as is depicted in Fig. 10 and described hereabove. Alternatively, the center support may be substituted with a more flexible wire between the attachment point D of the steering wires and the distal tip of the catheter.

Fig. 12 depicts an alternative center support member 190 of the present invention. The center support member 190 is formed with a constant width through attachment point D of the steering wire 138. Thereafter, a tapered section 192 proceeds distally to a distal end 194 having a tip 112 attached thereto. It will be appreciated that the center

support member 190 will possess different stiffness characteristics than the center support 180 depicted in Fig. 11. Such differing stiffness characteristics as will be provided by center support member 190 can find application in catheter end assemblies that are designed for specific purposes.

This catheter design also provides the capability for creating various lesion types. Long, transmural lesions may be created in the atria to cure atrial fibrillation or atrial flutter. The catheter 100 may be placed in intimate contact with any portion of the atrial endocardium to produce curvilinear lesions capable of curing atrial fibrillation. The steering modifications and distal section design described herein improve tissue contact when the catheter is prolapsed and reverse steered.

Discrete lesions may be created to treat other supraventricular tachycardias. Such lesions are created when a subset of the electrodes used to map the arrhythmia substrate are used to create the desired lesion thus terminating the arrhythmia substrate. By using the same electrodes(s) to create the lesion(s) as were used to map the substrate, more accurate lesion placement is assured and catheter repositioning required to map and ablate the substrate is reduced.

Large surface area, shallow lesions or large surface area, deep lesions may be created to ablate ventricular tachycardia substrates, especially those associated with monomorphic VT. By delivering radiofrequency energy to multiple electrodes positioned in intimate contact with the endocardium, time and temperature may be adjusted to create the desired lesion geometry.

Long, transmural lesions may also be created in the atria from an incision previously created during a surgical procedure to an anatomic barrier. Anatomic barriers are structures such as the tricuspid valve annulus, mitral valve

annulus, and vein orifices through which depolarization waveforms do not propagate. Depolarization waveforms may propagate around incisions and anatomic barriers producing reentrant tachyarrhythmias, but lesions connecting such structures reduce the potential for reentrant propagation patterns. Similar devices are taught in co-pending U.S. Patent Applications Serial Number 08/788,782, entitled Systems and Methods for Controlling Tissue Ablation using Multiple Temperature Sensing Elements, and Serial Number 08/769,856, entitled Loop Structures for Supporting Multiple Electrode Elements, the disclaimer of which are incorporated herein as though set forth in full.

Long, deep lesions created in the ventricles with the catheter 100 may be used to create lesions between infarcted regions (determined by reviewing intracardiac electrograms, impedance mapping, ultrasound, or other technique) or from an infarcted region to an anatomic structure to treat ventricular tachycardias. This may be especially be useful for polymorphic ventricular tachycardia substrates. Similar devices are taught in co-pending U.S. Patent Application Serial Number 08/738,822 entitled Systems and Methods for Visualizing Interior Regions of the Body, the disclosure of which is incorporated herein as though set forth in full.

Test of Invention:

The catheter 100 has been demonstrated to facilitate the creation of the atrial flutter lesion in vivo. In particular, electrodes were readily placed at the junction between the inferior vena cava and the tricuspid annulus. The steering created intimate contact with electrodes contacting the endocardial surface and caused electrodes to fill the Eustachian ridge. When radiofrequency energy was transmitted to all desired electrodes simultaneously, a contiguous lesion was created which was continuous in the subepicardial space.

The catheter 100 was also utilized to create ventricular lesions; in particular lesions were measured long (3 cm), and deep (> 7 mm). These lesion dimensions actually underestimated the actual lesion dimensions because the heart was dissected soon after lesion creation and the heart was grossly viewed for color changes without pathological staining. As a result, the actual lesion dimensions were greater than 1 cm. Still, the catheter 100 was easily placed on the endocardial surface and reverse steered to obtain intimate tissue contact through out the ablation electrodes and used to create long, deep lesions capable of curing ventricular tachycardia. In fact, the device 100 has enabled users to terminate ventricular tachycardia in three of three animal VT experiments having an infarct Model of VT.

A further improvement in catheter steering control of the present invention 10 is achieved through mechanisms for improving the transfer of torque forces from the handle 14 of the device 10 through the main body tube 18 to the distal assembly 22. The particular focus of the improvements in torque transfer are at the butt bond joint 32 between the main body tube 18 and the distal end assembly 22.

An enlarged cross-sectional view of the prior art butt bond joint assembly 240 is depicted in Figs. 13 and 14. The main body tube 18 is generally formed of a braided material for strength, pushability and efficient torque conduction throughout its length. A tubular steering mechanism guide coil 244 is disposed within the central lumen 246 of the main body tube 18 and a steering ferrule 248 is engaged to the distal end 250 of the guide coil 244. The steering ferrule 248 is formed with a steering wire bore 254 therethrough, such that steering wires 258 that are disposed within the guide coil 244 project through the bore 254 towards the distal end of the end assembly 22. A flat steering center support member 260 is disposed within a slot

262 that is formed through the distal portion of the ferrule 248. An insulating shrink tube 264 is formed around the steering mechanism which includes the distal portion of the guide coil 244, the ferrule 248, steering center support member 260 and steering wires 258. Other components, such as bundled electrode wires 266 and temperature sensor wires 268 may also be disposed within the lumen 246. The proximal end 26 of the distal end tubing 24 is adhesively butt bonded 32 to the distal end 28 of the main body tube 18. To provide strength to the butt bond 32, a tubular butt bond sleeve 274 is disposed within the butt bond joint assembly 240, and both the distal end 28 of the main body tube 18 and the proximal end 26 of the distal end tube 24 are adhesively bonded to the butt bond sleeve 274, in addition to being butt bonded to each other. A quantity of adhesive 280 is also inserted into the butt bond sleeve 274 to bond the steering mechanism sleeve 264 within the butt bond sleeve 274.

When the main body tube 18 is rotated it is desirable that the torque be communicated to the distal end assembly 22. To achieve this, the torque at the distal end 28 of the main body tube 18 is transferred to the distal end assembly 22 through the butt bond joint 240, primarily from the butt bonding sleeve 274, to the steering center support 260 through the adhesive 280 within the butt bond sleeve 274. Torque forces are also transferred from the main body tube 18, through the buff bond 32 to the proximal end 26 of the distal end tubing 24. Devices that improve the torque transfer are next discussed.

A first preferred embodiment of the torque transfer device of the present invention is depicted in Figs. 15 and 16, wherein Fig. 15 is an enlarged side elevational view, having cut away portions, and Fig. 16 is an end elevational view of the device depicted in Fig. 15. The significant difference between the prior art device depicted in Figs. 13

and 14 and the embodiment depicted in Figs. 15 and 16 is the addition of the generally oval crimp sleeve 290 that is disposed around the steering sleeve 264 within the butt bond sleeve 274. A quantity of adhesive 280, such as cyanoacrylate or an epoxy is injected into the butt bond sleeve 274 when the device is assembled, as discussed herebelow, and the adhesive 280 serves to bond all of the components together within the butt bond sleeve 274 and within the crimp sleeve 290, to provide improved torque transfer over the prior art device depicted in Figs. 13 and 14.

In the preferred embodiment, the crimp sleeve 290 is a cut length of metal hypodermic tubing or the like. In assembling the catheter 10, the guide coil 244, ferrule 248, center support member 260 and steering wires 258 are first assembled. The polyester shrink tube steering sleeve 264 is then placed over the assembly. The round crimp sleeve 290 is then placed over the steering sleeve 264 in the location of the butt bond 32 and crimped into an oval of appropriate size to fit over the steering assembly. The steering sleeve 264 is crimped to make a close fit with the steering assembly, but not pinch the steering wires 258, which would impede the steering capability of the device 10. The steering assembly with its guide coil 244 is then inserted into the main body tube 18, such that the crimp sleeve 290 of the steering assembly 18 is located at the butt bond location 32. The butt bond sleeve 274 is placed in position surrounding the crimp sleeve 290 while adhesive 280 is applied to the butt bond area. The adhesive 280 is injected between the butt bond sleeve 274 and the crimp sleeve 290, as well as within the crimp sleeve 290 exterior to the steering sleeve 264. The proximal end 26 of the distal tube 24 is then adhered to the butt bond sleeve 274 and to the distal end 28 of the main body tube 18 to complete the

assembly. Upon the hardening or curing of the adhesive, the improved torque transfer device 10 is completed.

The improved torque transfer features of the embodiment depicted in Figs. 15 and 16 over the prior art are a result of the increased mechanical interference between the center support 260 of the steering assembly within the crimp sleeve 290, together with the improved, metal to metal bond and improved mechanical keying of the crimp sleeve 290 within the butt bond sleeve 274. As a result of the utilization of the crimp sleeve 290, torque from the main body tube 18 is efficiently transferred through the butt bond sleeve 274 to the crimp sleeve 290 and ultimately to the center support 260 of the steering assembly. In the preferred catheter distal end assembly 22, the catheter tip 36 is fixedly engaged, such as by soldering, welding or adhesive bonding to the distal end of the center support 260. The torque is therefore efficiently transmitted to the tip 36, such that torque is applied to the distal tubing 24 at both its proximal end 26 at the butt bond 32 and the distal end at the catheter tip 36. This provides improved delivery of torque to various components, such as electrodes, that may be disposed in the distal end assembly 22 along the length of the distal tube 24.

A "C" or "U" shaped crimp sleeve 294 having a gap 296 in its sidewall 298 can be utilized in place of the tubular crimp sleeve 290 depicted in Figs. 15 and 16. Specifically, as depicted in Figs. 17 and 18, a "U" or "C" shaped crimp sleeve 294 can be placed around the steering sleeve 264 at the location of the butt bond 32 and crimped in place. Such a "U" or "C" shaped crimp sleeve 294 is somewhat easier to assemble than the tubular crimp sleeve 290 because it may be inserted laterally onto the steering sleeve 264, utilizing the sidewall gap 296 rather than being installed axially down the steering sleeve 264 as in the manner that the tubular crimp sleeve 290 must be installed.

A "G" shaped crimp sleeve 299 is depicted in Fig. 17A. The crimp sleeve 299 is formed with a generally spiral shaped gap 300 which becomes closed when the sleeve 299 is crimped around the steering assembly. The crimped sleeve 299 can therefore be thought of as a hybrid combination of the tubular crimp sleeve 290 and the "C" or "U" shaped crimp sleeve 294.

Figs. 19 and 20 depict an alternative butt bond sleeve 302 that may be utilized in the present invention, wherein Fig. 19 is a perspective view and Fig. 20 is an end elevational view similar to Fig. 16. The improved butt bond sleeve 302 is formed with a plurality of radially inwardly projecting ribs 306 that are parallel to the longitudinal axis of the generally cylindrical butt bond sleeve member 302. Four such ribs 306 are depicted in Figs. 19 and 20, however the sleeve invention is not to be so limited and fewer or more ribs are contemplated. As is best seen in Fig. 20, the rib members 306 provide additional torque transfer capability by providing a mechanical interaction with the outer portions 312 of the crimp sleeve 290. The space between the butt bond sleeve 102 and the crimp sleeve 290 is again preferably filled with adhesive 280.

To further aid in the transfer of torque to the center support member 260 of the steering assembly, the width of the center support member 260 may be increased within the butt bond area. A preferred center support configuration 318 is depicted in Fig. 21. It will be appreciated that the center support 318 is substantially identical to center support 180 depicted in Fig. 11. The center support 318 is formed with a relatively wide proximal end 320 for the efficient transfer of torque to the center support 318, a tapered central section 322 and a relatively narrow distal end 324. The relatively wide proximal end 320 serves to increase the mechanical keying of the center support 318 within the crimp sleeve 290, while the tapered central

section 322 and relatively thin distal section 324 provide a generally increased flexibility towards the distal end of the catheter distal end assembly 24, as compared to its proximal end. Such a varying flexibility throughout the length of the catheter distal end assembly 24 has been shown to provide improved catheter distal end steering and control properties. Therefore, a preferred embodiment of the present invention includes the tapered steering center support member 318 disposed within the crimp sleeve 290. In another alternative design the crimp sleeve 290 may be captured in a thermally formed bond between the main body tube 18 and the distal tube 24. The crimp sleeve would be embedded in the thermally melted wall formed inside the tube bond transition similar to being captured in the adhesive bond. This would also give you an enhanced mechanical interference fit for improved torque transfer. This design would be identical to Figs. 16 or 30 except for that the butt bond sleeve would be omitted.

Another alternative steering center support 330 of the present invention is depicted in Fig. 22. The center support 330 is formed with lateral extending portions 334 that are located along the proximal portion 336 of the center support 330 that will be disposed within the butt bond sleeve 274. The lateral extending portions 334 serve to provide even further mechanical interference and torque transfer when they are disposed within a crimp sleeve 290 than the previously described center supports 318 and 260. The center support 330 with the lateral extensions 334 also provides improved torque transfer over the prior art depicted in Figs. 13 and 14, even where a crimp sleeve 290 is not utilized. Specifically, as depicted in Fig. 23, the lateral extensions 334, even when just disposed within a steering sleeve 264, provide enhanced mechanical interference with the adhesive 280 disposed within the butt bond sleeve 274, over the prior art device depicted in Fig. 14.

To provide still improved torque transfer utilizing the center support 130 depicted in Fig. 22, a ribbed butt bond sleeve 302, as depicted in Fig. 8, may be utilized. Thus, as depicted in Fig. 24, the lateral extensions 334 of the center support 330, when disposed within the inwardly projecting ribs 306 of the butt bond sleeve 302, provide a mechanical interference that assures good torque transfer. As with previous embodiments, adhesive 280 is injected into the butt bond sleeve 302 in the assembly of the device.

Figs. 25, 26, 27 and 28 depict an alternative torque transfer device 360 of the present invention, wherein Fig. 25 is a perspective view, Fig. 26 is a top plan view, Fig. 27 is a side elevational view and Fig. 28 is an end elevational view. As depicted in Figs. 25 - 28 a stiffener member 364 is fixedly engaged, such as by soldering, spot welding or adhesive, to the distal end 250 of the guide coil 244. The stiffener 364 member has a rounded proximal portion 368 to facilitate its engagement with the guide coil 244, and a longitudinally projecting distal end portion 372. As depicted in Figs. 29 and 30 the end portion 372 projects distally alongside of the steering sleeve 264 which encloses the steering center support member 260 into the butt bond sleeve 274. Thereafter, when adhesive 280 is injected into the butt bond sleeve 274 to form the butt bond joint, as is done in the prior art device depicted in Figs. 13 and 14, the distal end 372 of the stiffener component 364 will be adhesively bonded into the butt bond sleeve 274. As a result, torque forces from the main body tube 18 are transferred through the butt bond sleeve 274 to the distal end 372 of the stiffener member 364 that is adhesively bonded within the butt bond sleeve 274. The torque is therefore transferred through the stiffener member 364 to the steering guide coil 244, through the ferrule 248 to the steering center support member 260, and thus to the catheter distal end assembly 22.

A further improvement in the torque transfer that is achieved through the use of the stiffener 364 is accomplished by utilizing a ribbed butt bond sleeve 380 that is similar to sleeve 302 depicted in Fig. 19. Specifically, as depicted in Fig. 31, the distal end 372 of the stiffener 364 will project between the inwardly projecting ribs 384 of a three ribbed butt bond sleeve 380 to provide a mechanical interference that will further assure good torque transfer in addition to the torque transfer through the adhesive 280 that is injected into the ribbed butt bond sleeve 380.

A further butt bond sleeve 390 that is utilizable with the stiffener 364 is depicted in Fig. 32. The butt bond sleeve 390 is formed with an extended rib-like portion that comprises an inwardly projecting sidewall portion 394 that forms an exterior channel 396. As depicted in Fig. 33, the channel 396 is disposed to cooperate with the distal end 372 of the stiffener 364, such that the distal end 372 resides within the channel 396 when the butt bond joint is made. Alternatively, as depicted in Fig. 34, a butt bond sleeve 398 having a gap or slot 400 in its sidewall which matingly engages the distal end 372 of the stiffener 364 can also be advantageously utilized where the diameter of the butt bond sleeve 390 is closer to the diameter of the guide coil 244.

Although the present invention has been described in terms of specific embodiments it is anticipated that alterations and modifications thereof will no doubt become apparent to those skilled in the art. It is therefore intended that the following claims be interpreted as covering all such alterations and modifications as fall within the true spirit and scope of the invention.

**Claims**

1. An improved catheter, comprising:

a handle;

a main body tube having a proximal end engaged to said handle and a distal end;

a distal end assembly including a distal end tubular member having a proximal end and a distal end;

a steering mechanism being disposed within said distal end tubular member, said steering mechanism including a center support member having a proximal end portion and a distal end portion, and at least one steering wire being engaged to said center support member;

said distal end assembly being engaged to said main body tube through a butt bond joint assembly, said butt bond joint assembly including a bonded engagement of said proximal end of said distal end tubular member and said distal end of said main body tube;

said butt bond joint assembly including a butt bond sleeve member being disposed partially within said main body tube and partially within said distal end tubular member and being bonded to both said main body tube and said distal end tubular member;

said proximal end portion of said center support member being disposed within said buff bond sleeve;

a quantity of adhesive material being disposed within said butt bond sleeve and acting to engage said center support member within said butt bond sleeve;

and wherein said butt bond joint assembly further includes a torque transfer enhancement means, being engaged with portions of said steering mechanism and disposed within said adhesive that is disposed within said butt bond sleeve to enhance the transfer of torque forces from said distal end of said main body tube to said center support member.

2. A device as described in claim 1 wherein said torque transfer enhancement means includes a crimp sleeve member being disposed around portions of said proximal end of said center support member within said butt bond sleeve, and in contact with said adhesive disposed within said butt bond sleeve.

3. A device as described in claim 2 wherein said crimp sleeve member comprises a tubular sleeve.

4. A device as described in claim 2 wherein said crimp sleeve member comprises a U-shaped sleeve.

5. A device as described in claim 2 wherein said crimp sleeve member comprises a C-shaped sleeve.

6. A device as described in claim 2 wherein said crimp sleeve member comprises a G-shaped sleeve.

7. A device as described in claim 1 wherein said torque transfer enhancement means includes a stiffener member being fixedly engaged to said steering mechanism and projecting within said butt bond sleeve in contact with said adhesive disposed within said butt bond sleeve.

8. A device as described in claim 7 wherein said stiffener member comprises a generally flat member having a curved portion that is engaged to said steering mechanism and a distally projecting arm portion that projects within said butt bond sleeve.

9. A device as described in claim 1 wherein said torque enhancement means includes a laterally extending portion of said proximal end of said center support member, said laterally extending portion being disposed within said

butt bond sleeve and within said adhesive that is disposed within said butt bond sleeve.

10. A device as described in claim 1 wherein said torque transfer enhancement means further includes at least one butt bond sleeve rib member, said rib member projecting radially inwardly from said butt bond sleeve and into said adhesive disposed within said butt bond sleeve.

11. A device as described in claim 2 wherein said torque transfer enhancement means further includes at least one butt bond sleeve rib member, said rib member projecting radially inwardly from said butt bond sleeve and into said adhesive disposed within said butt bond sleeve.

12. A device as described in claim 7 wherein said torque transfer enhancement means further includes at least one butt bond sleeve rib member, said rib member projecting radially inwardly from said butt bond sleeve and into said adhesive disposed within said butt bond sleeve.

13. A device as described in claim 9 wherein said torque transfer enhancement means further includes at least one butt bond sleeve rib member, said rib member projecting radially inwardly from said butt bond sleeve and into said adhesive disposed within said butt bond sleeve.

14. A device as described in claim 1 wherein said center support member includes a relatively wide proximal portion, a tapered central portion and a relatively narrow distal portion.

15. A device as described in claim 14 wherein said steering wire is engaged to said distal portion of said center support member a sufficient distance away from said

distal end of said center support member to provide a straight distal end portion of said distal end assembly when said steering wire is activated to cause bending of said distal end assembly.

16. A device as described in claim 15 wherein said steering wire is engaged to said center support member at a distance of approximately one inch away from said distal end of said center support member.

17. An improved steering mechanism for a catheter distal end assembly, comprising:

a steering center support member having a distal end and being disposed within said catheter distal end assembly;

at least one steering wire being engaged to said center support member a sufficient distance away from said distal end of said center support member to provide a straight distal end portion of said distal end assembly when said steering wire is activated to cause bending of said distal end assembly.

18. A device as described in claim 17 wherein said center support member includes a relatively wide proximal portion, a tapered central portion and a relatively narrow distal portion, and wherein said steering wire is engaged to said relatively narrow distal portion of said center support member.

19. A device as described in claim 18 wherein said steering wire is engaged to said center support member at a distance of approximately one inch away from said distal end of said center support member.

20. A device as described in claim 17 wherein said center support member includes a relatively wide proximal portion

portion and a tapered distal portion, and wherein said steering wire is engaged to said relatively wide proximal portion and said center support member.

21. A device as described in claim 1 wherein said center support member includes a relatively wide proximal portion and a tapered distal portion.

22. A system for ablating body tissue comprising

a catheter body having an elongated axis and a distal assembly carrying at least two electrodes, and including a steering mechanism adapted to contact body tissue along the length of said distal assembly;

at least two electrodes supported by the distal assembly capable of creating generally elliptical lesions at least 2 cm long and 7 mm deep which are substantially uniform in depth when a source of radiofrequency energy conveys radiofrequency energy to the at least two electrodes simultaneously;

whereby transmission of radiofrequency energy simultaneously by the at lest two electrodes forms a lesion that extends without interruption across the body tissue area between the at least two electrodes.

23. A system described in claim 22 wherein actuation of said steering mechanism causes the distal assembly carrying electrodes to contact body tissue within the crevasse between the inferior vena cava and tricuspid annulus.

24. A system described in claim 22 wherein actuation of said steering mechanism causes the distal assembly carrying electrodes to exert increased force against body tissue.

25. A system described in claim 22 wherein the lesion is created from an infarcted region of body tissue to an anatomic barrier.

26. A system described in claim 22 wherein the lesion is created from at least two infarcted regions of body tissue.

27. A system described in claim 22 wherein the lesion is created from a surgical incision to an anatomic barrier.

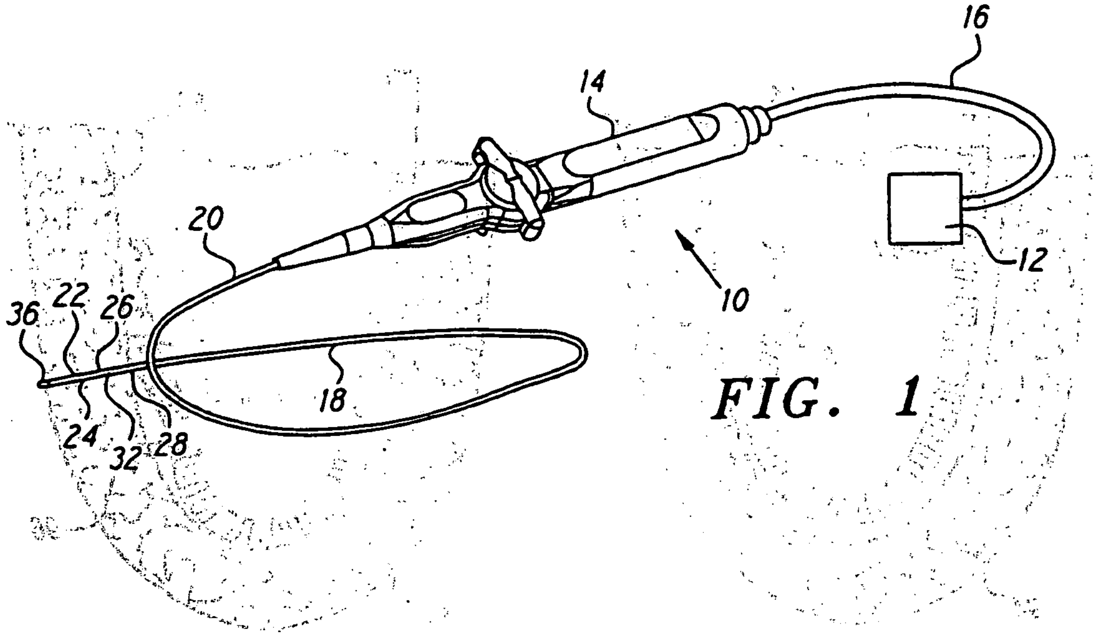



FIG. 1

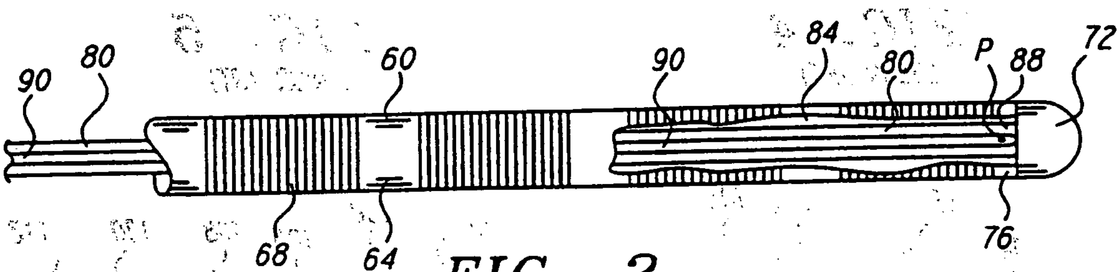



FIG. 2
(PRIOR ART)

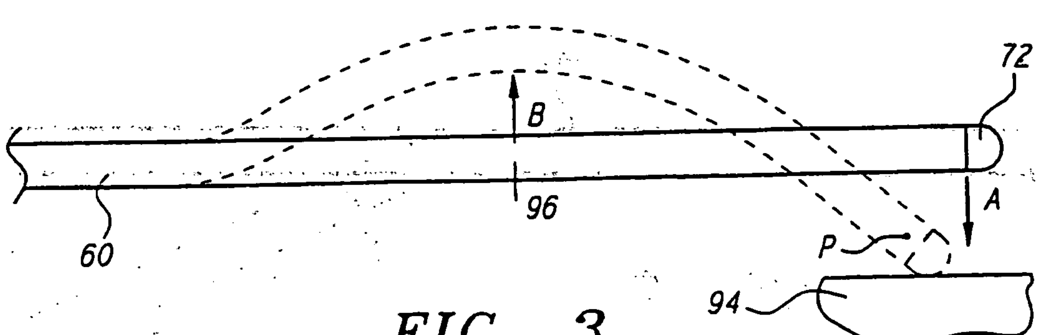



FIG. 3
(PRIOR ART)

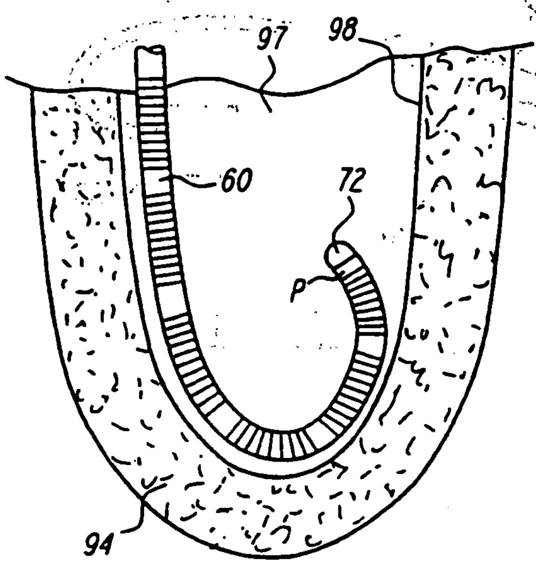



FIG. 4
(PRIOR ART)

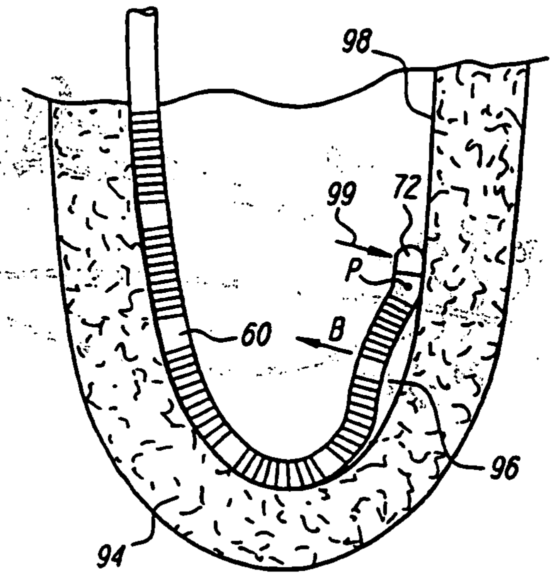



FIG. 5
(PRIOR ART)

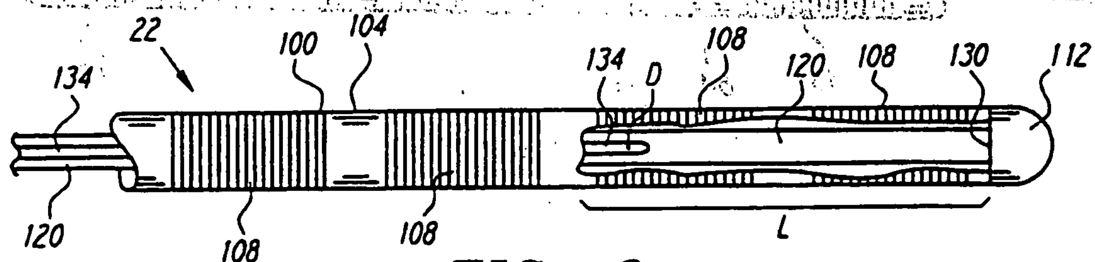



FIG. 6

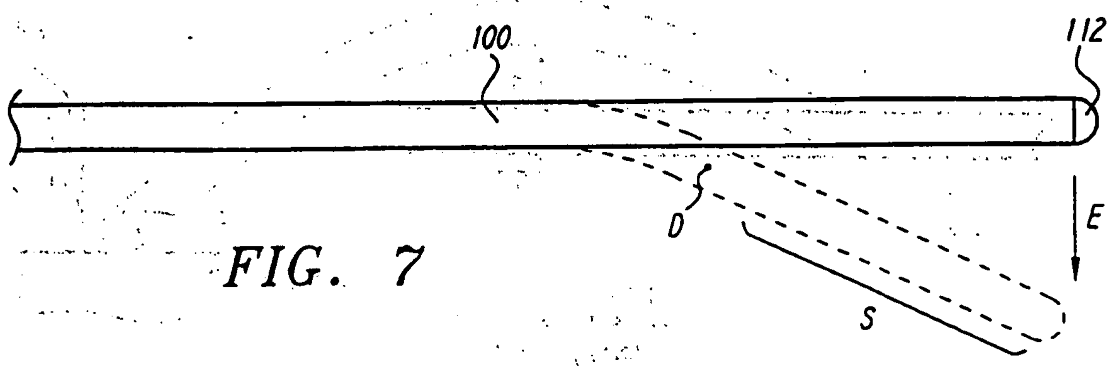



FIG. 7

3/11

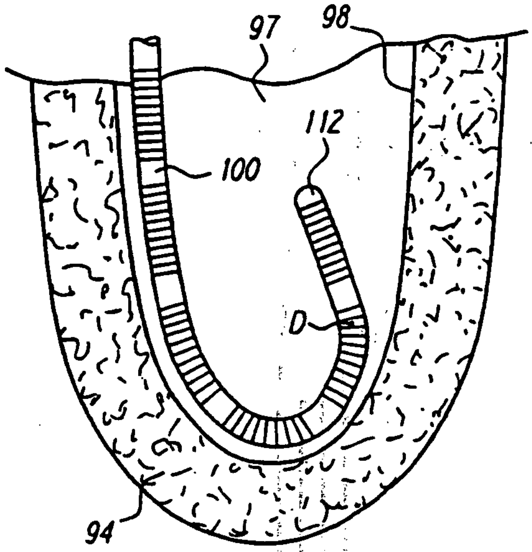



FIG. 8

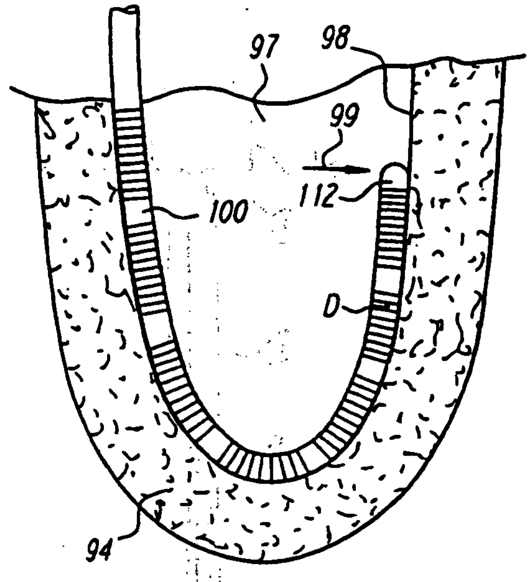



FIG. 9

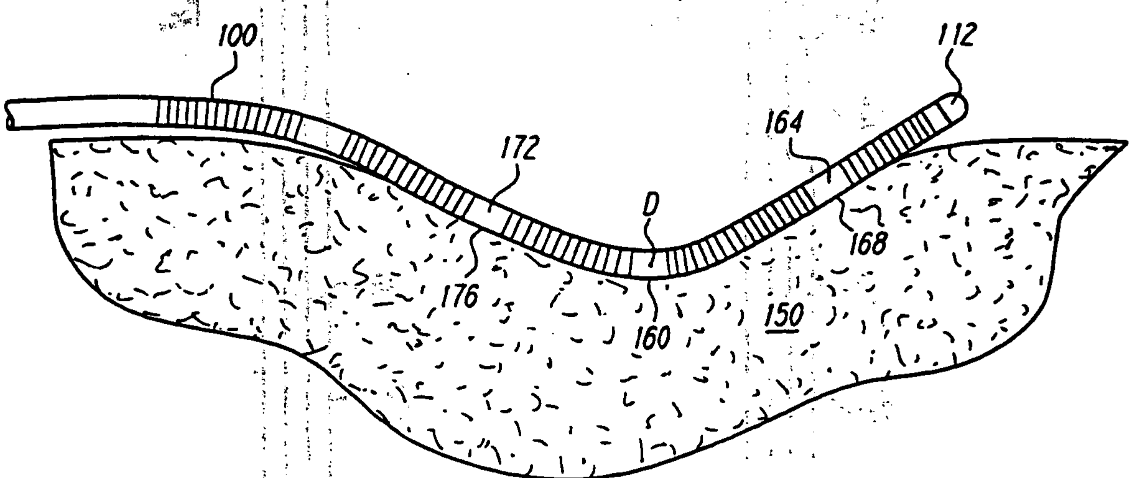



FIG. 10

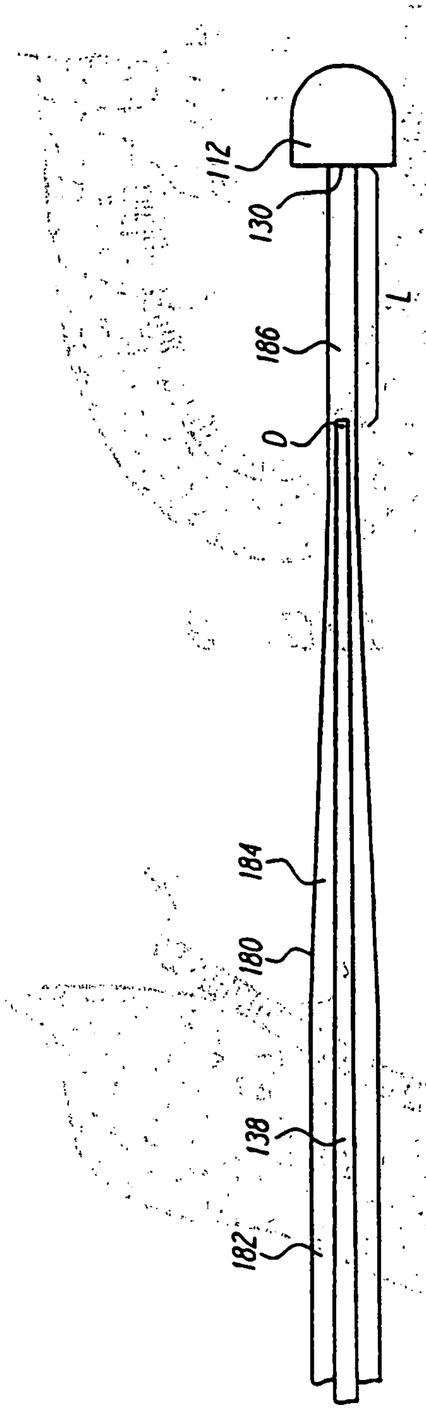



FIG. 11

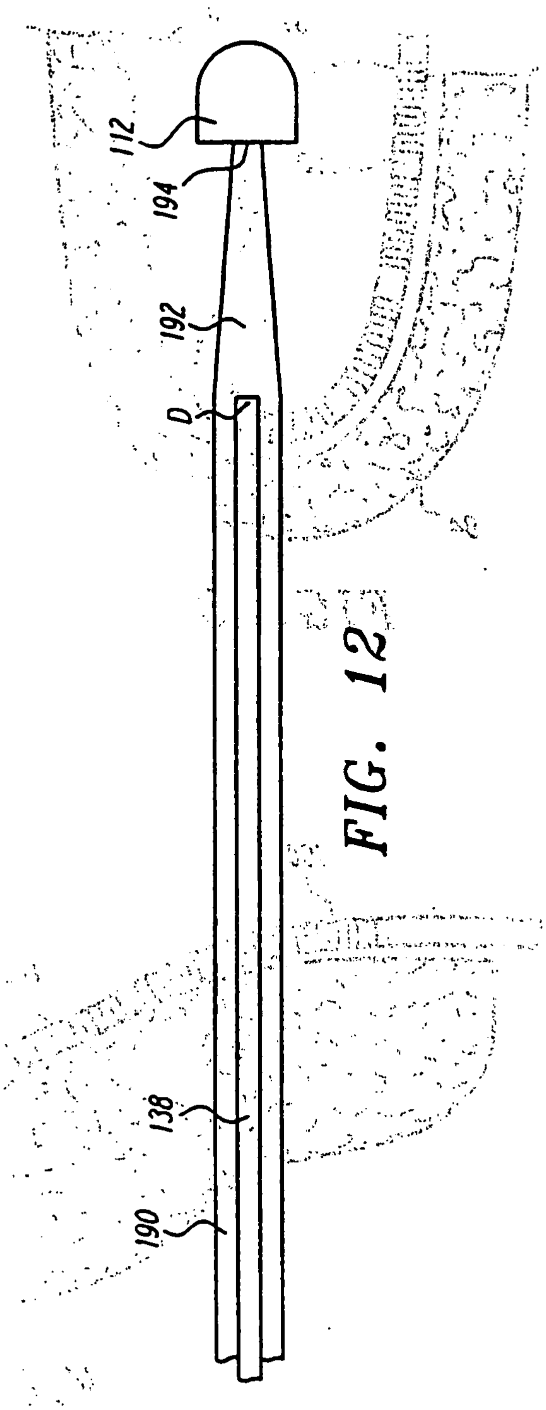
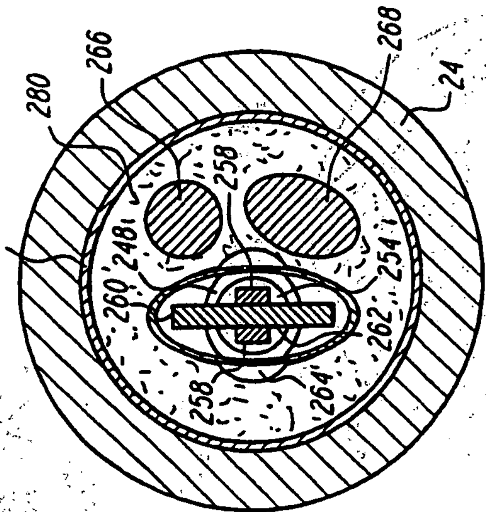



FIG. 12


266
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268
24
258
274
248
254
260
262
258
264

FIG. 14

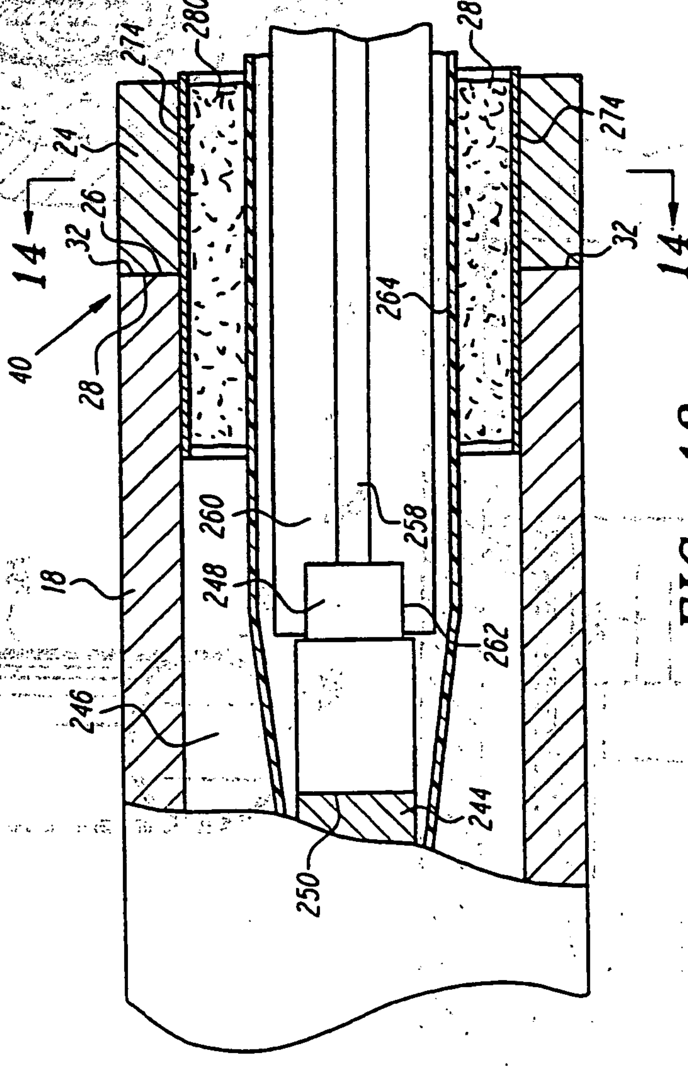
274
280
280
24
274
14
26
32
32
14
40
28
264
260
258
248
18
262
246
244
250

FIG. 13

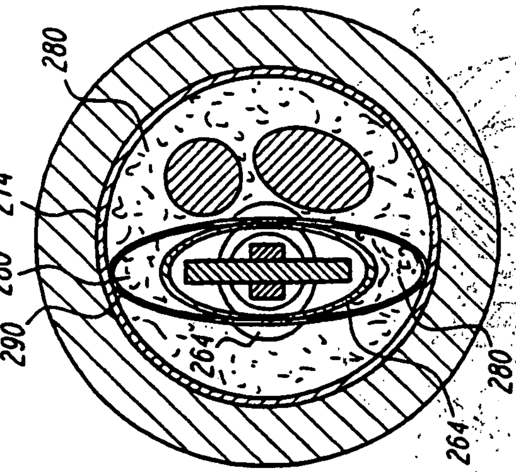


FIG. 16

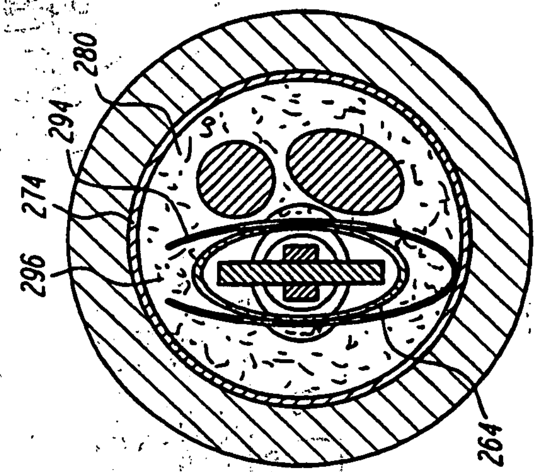


FIG. 18

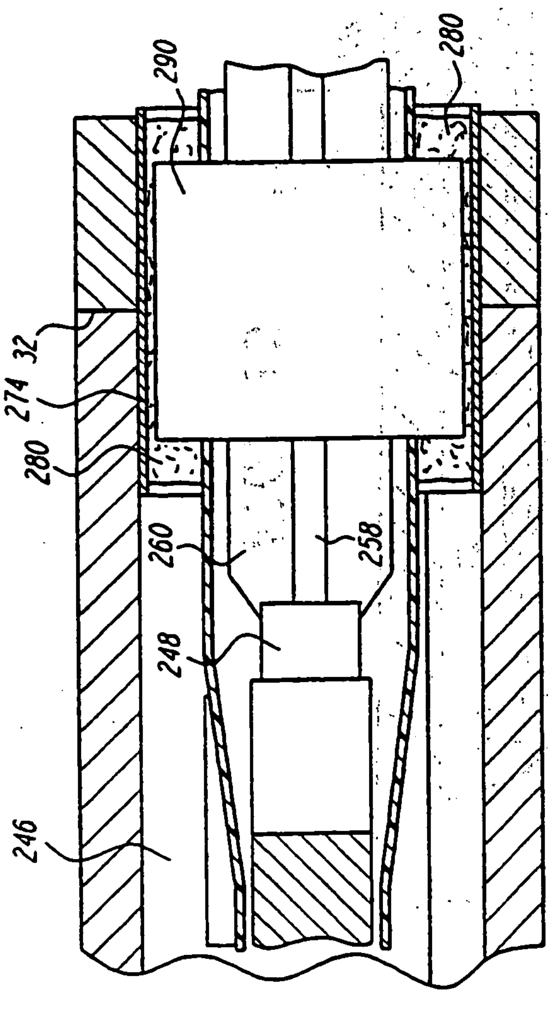


FIG. 15

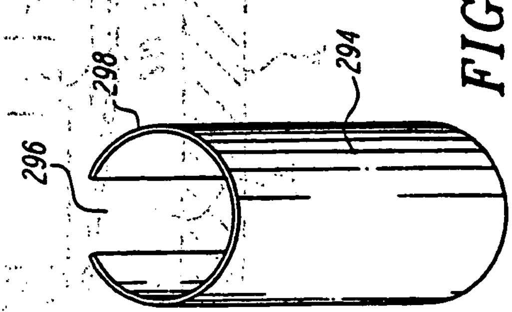


FIG. 17

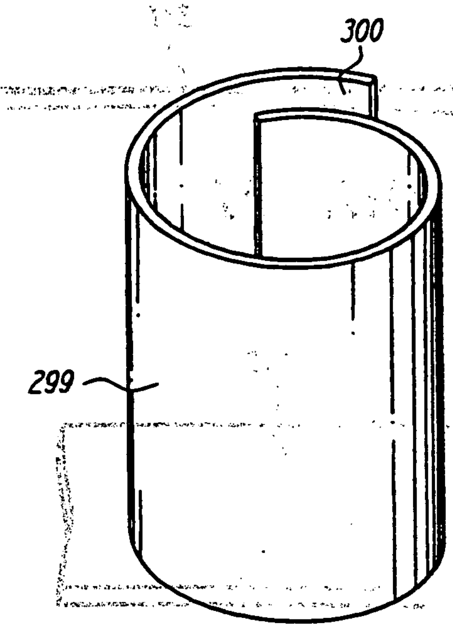


FIG. 17A

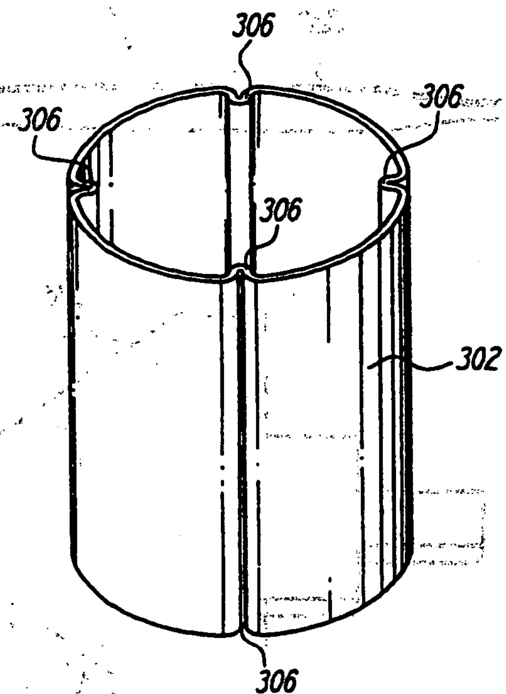


FIG. 19

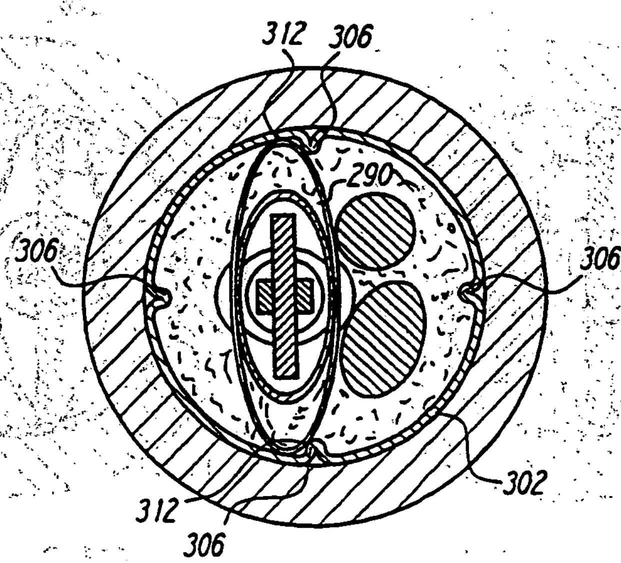


FIG. 20

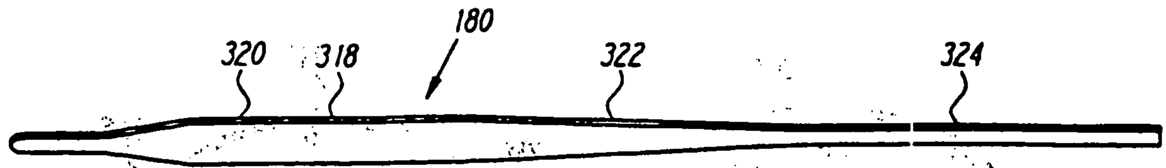


FIG. 21

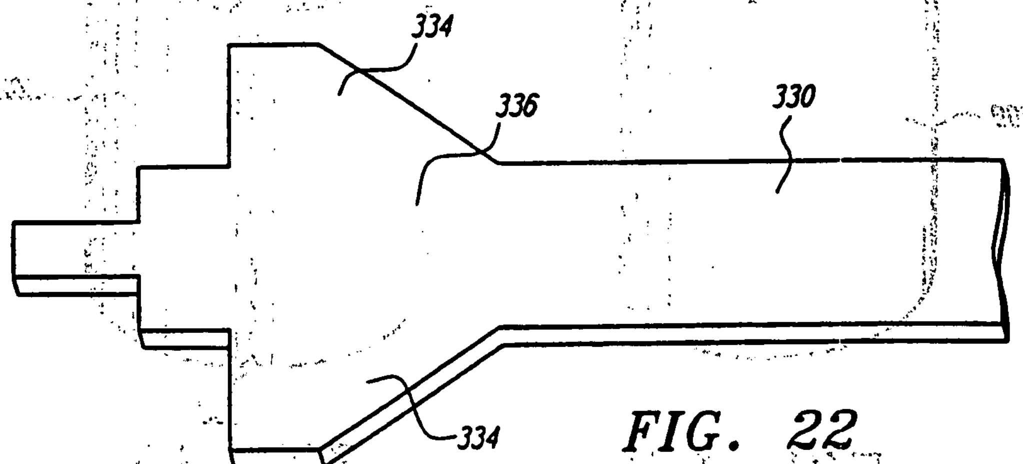


FIG. 22

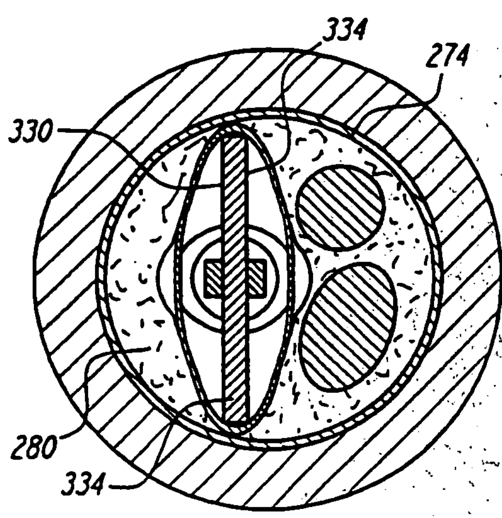


FIG. 23

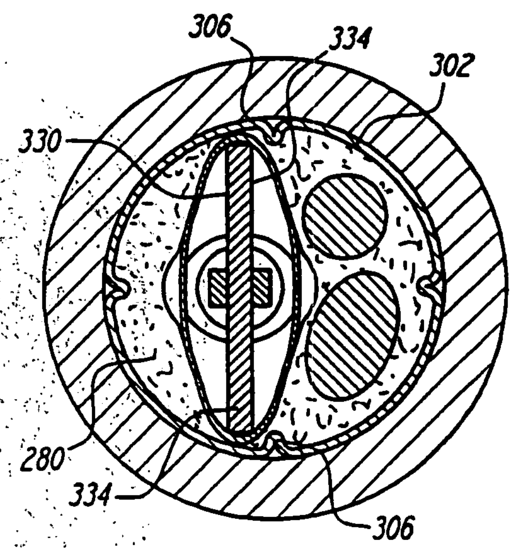


FIG. 24

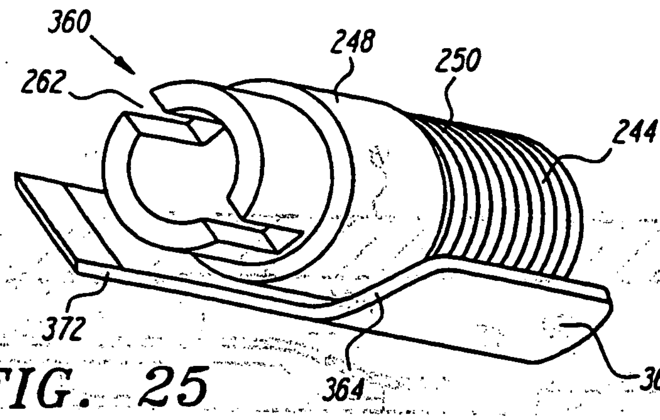


FIG. 25

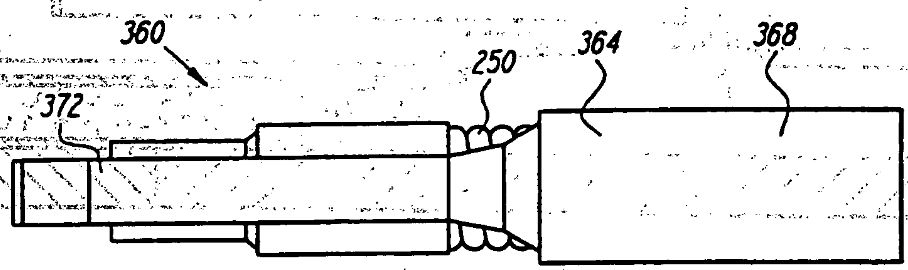


FIG. 26

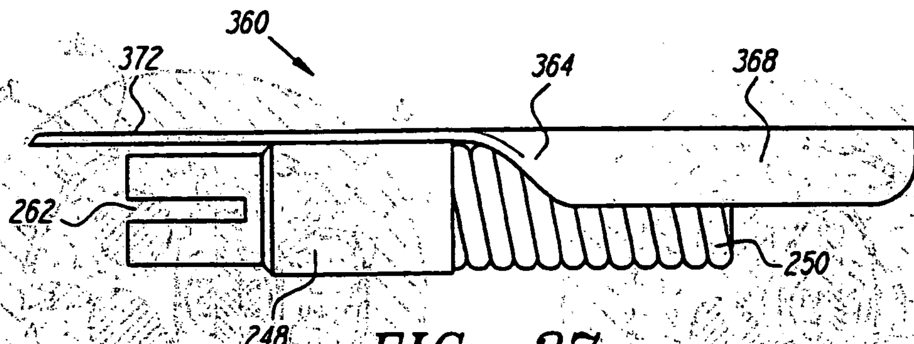


FIG. 27

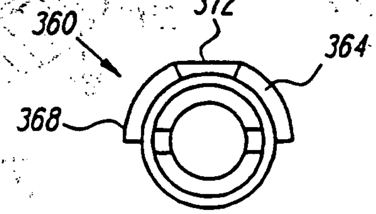


FIG. 28

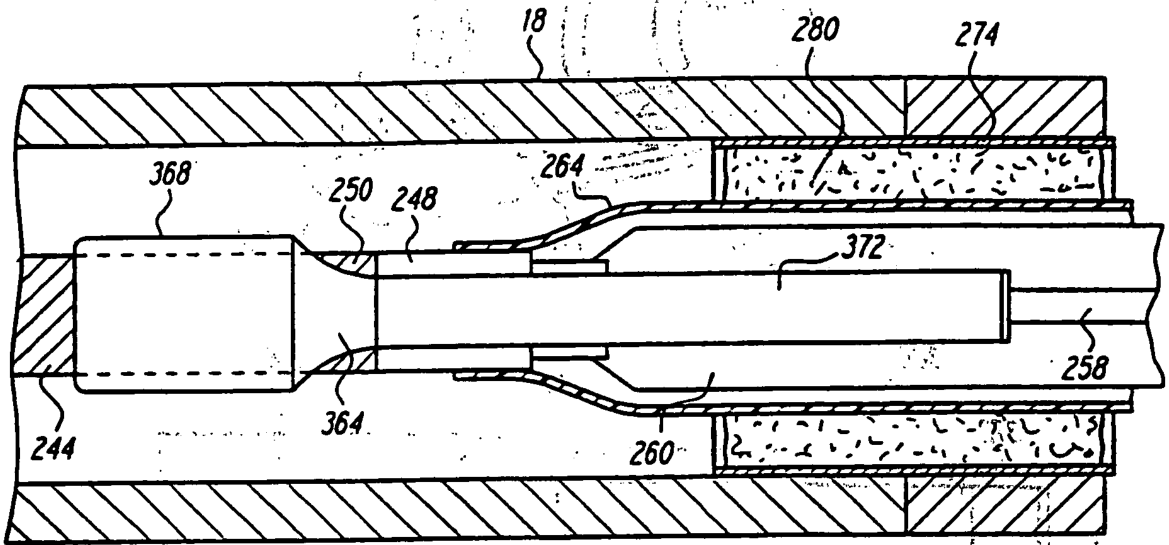


FIG. 29

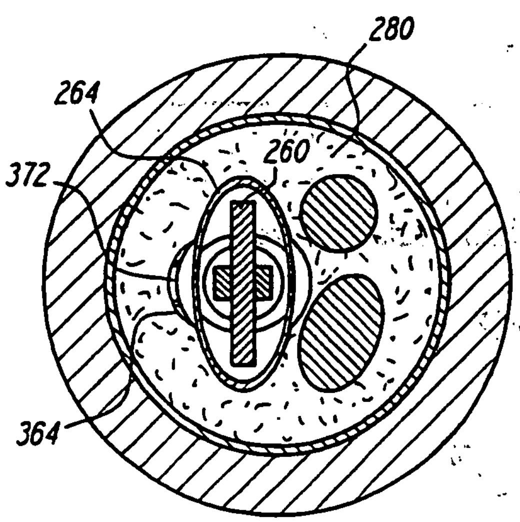


FIG. 30

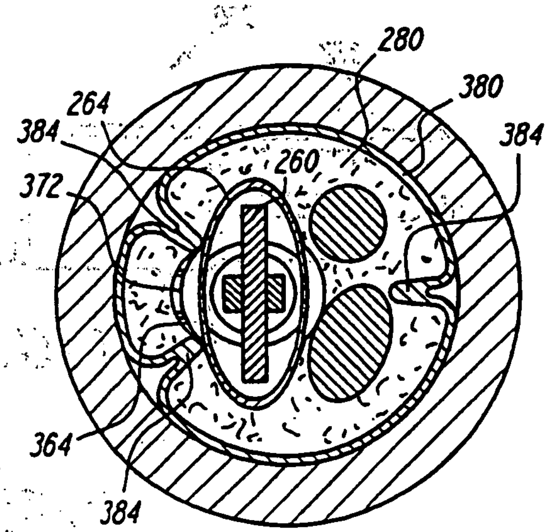


FIG. 31

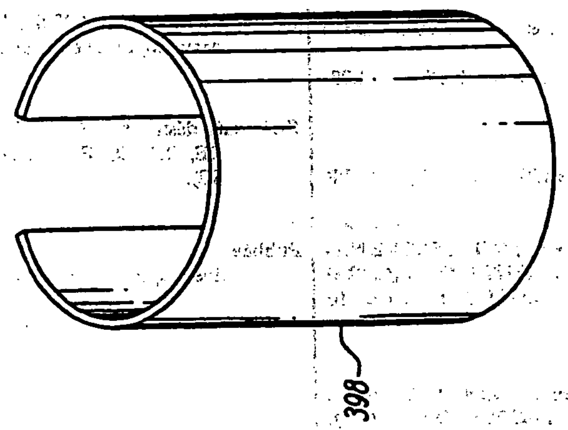


FIG. 34

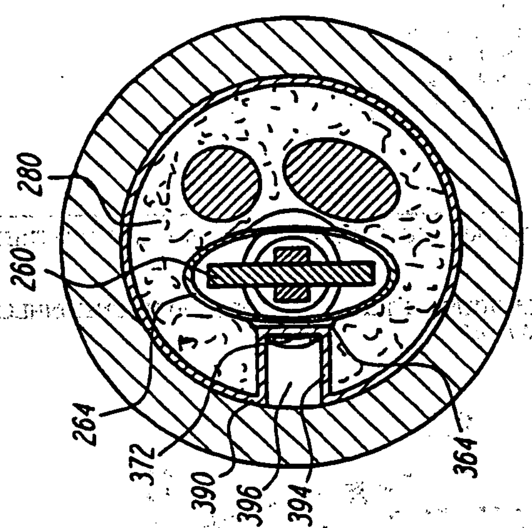


FIG. 33

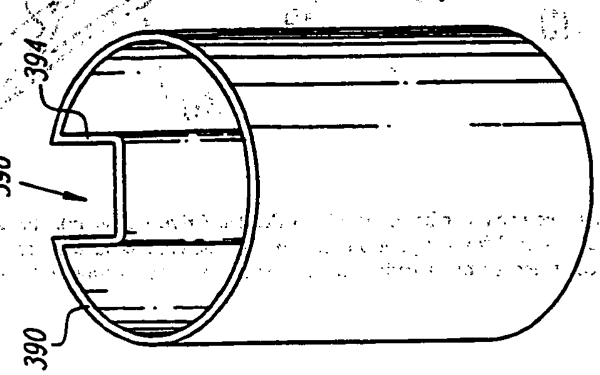


FIG. 32